

**STATE OF TENNESSEE  
DEPARTMENT OF HEALTH**

<b>IN THE MATTER OF:</b>	)	<b>BEFORE THE TENNESSEE BOARD</b>
	)	<b>OF MEDICAL EXAMINERS</b>
<b>KEN D. BERRY, M.D.</b>	)	
<b>RESPONDENT</b>	)	<b>CASE NO: 2017006511</b>
	)	
<b>CAMDEN, TENNESSEE</b>	)	
<b>TENNESSEE LICENSE NO.: 35476</b>	)	

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**CONSENT ORDER**

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Comes now the Division of Health Related Boards of the Tennessee Department of Health (hereinafter the "Division"), by and through the Office of General Counsel, and Respondent Ken D. Berry, M.D. (hereinafter "Respondent"), who would respectfully move the Tennessee Board of Medical Examiners (hereinafter the "Board") for approval of this Consent Order affecting Respondent's medical license in the State of Tennessee.

The Board is responsible for the regulation and supervision of medical doctors licensed to practice in the State of Tennessee. See Tennessee Medical Practice Act, Tennessee Code Annotated Section (hereinafter "TENN. CODE ANN. §") 63-6-101, *et seq.* It is the policy of the Board to require strict compliance with the laws of this State, and to apply the laws so as to preserve the quality of medical care provided in Tennessee. It is the duty and responsibility of the Board to enforce the Tennessee Medical Practice Act in such a manner as to promote and protect the public health, safety and welfare in every practicable way, including disciplining medical doctors who violate the provisions of TENN. CODE ANN. § 63-6-101, *et seq.* or the Rules and Regulations promulgated by the Board and recorded in the Official Compilation Rules and Regulations of the State of Tennessee (hereinafter "TENN. COMP. R. & REGS.").

Respondent, by his signature to this Consent Order, waives the right to a contested case hearing and any and all rights to judicial review in this matter. Respondent agrees that

presentation to and consideration of this Consent Order by the Board for ratification and all matters divulged during that process shall not constitute unfair disclosure such that the Board or any of its members shall be prejudiced to the extent that requires their disqualification from hearing this matter should this Order not be ratified. Likewise, all matters, admissions and statements disclosed or exchanged during the attempted ratification process shall not be used against Respondent in any subsequent proceeding unless independently entered into evidence or introduced as admissions.

Respondent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of or to challenge or contest the validity of this Consent Order. Respondent understands that by signing this Consent Order, Respondent is allowing the Board to issue its order without further process. Respondent acknowledges that this is a formal disciplinary action and will be reported to the Health Integrity and Protection Data Bank and/ or similar agency. In the event that the Board rejects this Consent Order for any reason, it will be of no force or effect for either party.

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## **I. STIPULATIONS OF FACT**

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- 1) Respondent has been at all times pertinent hereto licensed by the Board as a medical doctor in the State of Tennessee, having been granted Tennessee medical license number 35476 by the Board on June 21, 2001, which has a current expiration date of December 31, 2018.
- 2) Respondent's license is currently on probation pursuant to a May 18, 2016 board order which disciplined Respondent for prescribing controlled substances and other medications without following the prerequisites to issuing prescriptions outlined in the Board's rules. Respondent was also disciplined for prescribing to family members.

- 3) Respondent owns and operates The Berry Clinic located in Camden, Tennessee.
- 4) Respondent performs procedures such as punch biopsies, cryotherapy, simple fractures, joint and trigger point injections, electrocardiograms, pulmonary function testing and testosterone and estrogen pellet injections.
- 5) Respondent also maintains a second clinic inside The Berry Clinic called "The Upstairs." In this area Respondent performs Botox injections, collagen induction therapy and dermal fillers.
- 6) Respondent injected testosterone and estradiol pellets into patients by reusing stainless steel injection devices (trocars) that are manufactured and sold for single use per the Food and Drug Administration. Respondent avers that the representative for the trocar manufacturer advised reuse of the trocar devices. Respondent reused trocars in testosterone and estradiol pellet injections from approximately 2011 to 2017.
- 7) During an inspection of the Respondent's clinic in May 2017, it was discovered that the cleaning, disinfection and sterilization practices at the clinic were inadequate according to CDC guidelines to properly prevent the transmission of infectious agents during insertion procedures as described above in Paragraph 6.
- 8) The clinic's written policy describes cleaning instruments under warm tap water and then placing the instruments into a tray that contains an industrial strength disinfectant. The instruments would then soak for a period of time that ranged from ten minutes to two weeks. The instruments were then removed from the tray, rinsed off with sterile water, placed on a sterile towel to dry and then sealed in packets. The instruments were not steam sterilized prior to placement in the packets.
- 9) Respondent does not have an autoclave in the clinic and admitted that he had not used heat sterilization on any of his instruments used for patient care; potentially exposing

patients to microorganisms that come in contact with body tissues and fluid; increasing the potential for the transmission of diseases from patient to patient.

- 10) Following the Department of Health's investigation into this matter, Respondent implemented a new policy for the insertion of testosterone and estradiol pellet injections using single use trocars only one time, and then disposing of the trocar following the procedure.
- 11) Respondent posted a video advertising a cosmetic facial procedure referred to as a "vampire facial" on The Upstairs Clinic's Facebook page. The video shows the Respondent's staff member demonstrating the procedure on the Respondent.
- 12) The procedure involves placing numbing cream on a patient's face and drawing blood from the patient. The patient's blood is placed in a centrifuge to isolate the platelets from the blood and then smeared onto the patient's face. A microneedling pen is then used on the patient's face to puncture their skin. The video shows minimal adherence to routine infection prevention precautions. The handle of the microneedling pen was not covered with a disposable sleeve in the video, and was potentially contaminated with the patient's blood from the gloved hands of the staff member. The Berry Clinic no longer offers "vampire facials" as part of the services provided at The Upstairs of the Berry Clinic.
- 13) Immunizations and a urine sample that did not contain a patient name were stored in a small refrigerator inside the onsite laboratory facility that also contained food items. This onsite lab is staffed by LabCorp, who is an independent contractor of The Berry Clinic.
- 14) A prescription bottle of Clonidine HCL 0.1 mg with an expiration date of February 26, 2014 was found in a lab within the clinic. The expired medication had been self-prescribed by the Respondent. This was a stock bottle maintained at the office to address immediate blood pressure needs for patients. Respondent avers this prescription was

ordered for office use, and that he did not prescribe this medication for his personal use, nor did he take this medication himself.

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## **II. GROUNDS FOR DISCIPLINE**

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The facts stipulated to in the Stipulations of Fact are sufficient to establish that grounds for discipline of Respondent's medical license exist. Specifically, Respondent has violated the following statutes or rules which are part of the Tennessee Medical Practice Act, (TENN. CODE ANN. § 63-6-101, *et seq.*) for which disciplinary action before and by the Board is authorized:

- 14) The facts stipulated in paragraphs six (6) through thirteen (13) *supra*, constitute a violation of TENN. CODE ANN. § 63-6-214 (b) (1):

Unprofessional, dishonorable or unethical conduct

- 15) The facts stipulated in paragraphs six (6) through twelve (12) *supra*, constitute a violation of TENN. COMP. R. & REGS. 0880-02-.14-- Universal Precautions For The Prevention Of HIV Transmission

The Board adopts, as is fully set out herein, rules 1200-14-03-.01 through 1200-14-03-.03 inclusive, of the Department of Health and as they may from time to time be amended, as its rule governing the process for implementing universal precautions for the prevention of HIV transmission for health care workers under its jurisdiction

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## **III. POLICY STATEMENT**

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The Tennessee Board of Medical Examiners takes this action in order to protect the health, safety and welfare of the people of the State of Tennessee and ensure that the public confidence in the integrity of the medical profession is preserved.

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#### IV. ORDER

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NOW THEREFORE, Respondent, for the purpose of avoiding further administrative action with respect to this cause, agrees to the following:

- 17) The probationary status placed on the Tennessee medical license of **Ken D. Berry, M.D.**, license number 35476 pursuant to the May 2016 Order, is hereby extended for a period of two (2) years following the expiration of the initial period of probation. Respondent must petition the Board for an Order of Compliance and personally appear before the Board for the probation to be lifted unless his appearance is waived by the Board's medical director.
- 18) Respondent must obtain a certified infection preventionist to develop and maintain a comprehensive infection control plan that adheres to the minimum standards as outlined by the Centers for Disease Control and Prevention's *"Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care."*
- 19) The infection control plan must also outline appropriate cleaning, disinfection and sterilization of surgical instruments that adheres to the minimum standards as outlined by the Centers for Disease Control and Prevention taking into account the safety of both patients and staff. Respondent must submit the infection control plan to the Board's medical director within thirty (30) days of the effective date of this Order.
- 20) During the probationary period, Respondent must have an annual on-site inspection completed by a certified infection preventionist and have the certified infection preventionist submit an annual report detailing the findings of the inspection to the Board's medical director. The first annual report will be due one year from the effective date of this Order.

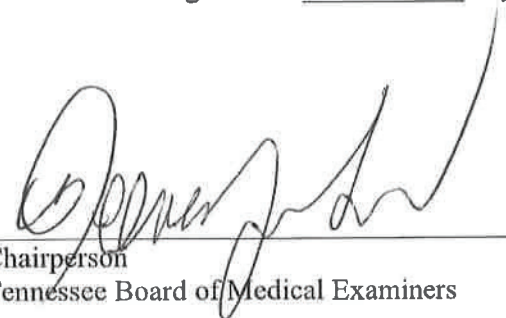
- 21) During the probationary period, Respondent must also submit a quarterly report to the Board's medical director detailing his adherence to the infection control plan developed by the certified infection preventionist beginning three months after the effective date of this Order.
- 22) Within three (3) months of the effective date of this Order, Respondent must enroll in and successfully complete ten (10) continuing medical education hours in the area of infection control. All continuing medical education courses must be pre-approved by the Board's medical director prior to Respondent enrolling in the course. Within thirty (30) days after completion of the ten (10) continuing medical education hours, Respondent shall mail or deliver proof of compliance with this course requirement to: **Disciplinary Coordinator, The Division of Health Related Boards, Tennessee Department of Health, 665 Mainstream Drive, Nashville, Tennessee 37243.** A notation shall be placed on said proof that it is for Ken D. Berry, M.D., Complaint No. 2017006511. Any continuing medical education hours earned from attendance and completion of the course required by this paragraph shall be in addition to the continuing medical education hours required to maintain licensure.
- 23) Respondent must pay one (1) Type A civil penalty, in the amount of one thousand dollars (\$1,000.00), for reusing a single-use stainless steel injection device as outlined in paragraph six (6) of the Stipulations of Fact, *supra*.
- 24) Respondent must pay one (1) Type A civil penalty, in the amount of one thousand dollars (\$1,000.00), for failing to properly clean, disinfect and sterilize medical instruments as outlined in paragraphs seven (7) through nine (9) of the Stipulations of Fact, *supra*.



- 25) Respondent must pay one (1) Type A civil penalty, in the amount of one thousand dollars (\$1,000.00), for failing to utilize infection prevention precautions as outlined in paragraphs eleven (11) and twelve (12) of the Stipulations of Fact, *supra*.
- 26) Respondent must pay, pursuant to Tenn. Code Ann. §§ 63-6-214 (k) and 63-1-144(a)(4), the actual and reasonable costs of prosecuting this case to the extent allowed by law, including all costs assessed against the Board by Office of Investigations, Secretary of State, Administrative Procedures Division as well as the Office of General Counsel in connection with the prosecution of this matter. These costs will be established by an Assessment of Costs prepared and filed by counsel for the Department. Said costs shall not exceed ten thousand dollars (\$10,000.00) ten thousand dollars. Any and all costs shall be paid in full within one (1) year from the issuance of the Assessment of Costs by submitting a certified check, cashier's check, or money order payable to the **State of Tennessee**, which shall be mailed or delivered to the address listed below. A notation shall be placed on said check that it is payable for the costs of Ken D. Berry, MD Case No. 2017006511.
- 28) Any and all civil penalties shall be paid within sixty (60) days of the effective date of this Consent Order. Any and all civil penalty payments shall be paid by certified check, cashier's check, or money order payable to the **State of Tennessee**, which shall be mailed or delivered to: **Disciplinary Coordinator, The Division of Health Related Boards, Tennessee Department of Health, 665 Mainstream Drive, Nashville, Tennessee 37243**. A notation shall be placed on said check that it is payable for the civil penalty of Ken D. Berry, MD Case No. 2017006511.
- 29) Respondent understands that this is a formal disciplinary action and will be reported to the National Practitioner Data Bank (NPDB) and/or similar agency.




This **CONSENT ORDER** was approved by a majority of a quorum of the Tennessee Board of Medical Examiners at a public meeting of the Board and signed this 24<sup>th</sup> day of January, 2018

  
Chairperson  
Tennessee Board of Medical Examiners


**APPROVED FOR ENTRY:**

  
Ken D. Berry, M.D.  
Respondent

12/11/2017  
DATE

  
Alex Scarbrough Fisher (B.P.R. # 031391)  
Attorney for Respondent  
Frost Brown Todd LLC  
The Pinnacle at Symphony Place  
150 3rd Avenue South | Suite 1900  
Nashville, TN 37201  
(615) 251-5594

12/20/17  
DATE

  
Jennifer L. Putnam (B.P.R. #029890)  
Assistant General Counsel  
Tennessee Department of Health  
665 Mainstream Drive  
Nashville, Tennessee 37243  
(615) 741-1611

1/9/18  
DATE

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a true and correct copy of this document has been served upon Respondent, by and through counsel, Alexandria S. Fisher, Esq. at 150 3rd Ave S #1900, Nashville, TN 37201 by delivering same in the United States Mail, Certified Number 7016 0600 0000 6508 1437, return receipt requested, and United States First Class Postage Pre-Paid Mail, with sufficient postage thereon to reach its destination.

This 25<sup>th</sup> day of January, 2017.

Jennifer L. Putnam  
Jennifer L. Putnam  
Assistant General Counsel